Docket No.: 1895-SPL
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Craig A. Kelly

Application No.: 10/687,230 Confirmation No.: 8063

Filed: October 16, 2003 Art Unit: 3737

For: Non-Invasive Health Monitor Examiner: James M. Kish

APPEAL BRIEF

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

As required under § 41.37(a), this brief is filed within two months of the Notice of Appeal filed in this case on April 17, 2008, and is in furtherance of said Notice of Appeal.

The fees required under § 41.20(b)(2) are dealt with in the accompanying TRANSMITTAL OF APPEAL BRIEF.

This brief contains items under the following headings as required by 37 C.F.R. § 41.37 and M.P.E.P. § 1205.2:

I.	Real Party In Interest
II	Related Appeals and Interferences
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I. REAL PARTY IN INTEREST

The real party in interest for this appeal is: The Johns Hopkins University.

II. RELATED APPEALS AND INTERFERENCES

There are no other appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

A. Total Number of Claims in Application

There are 47 claims pending in application.

B. Current Status of Claims

1. Claims canceled. None.
2. Claims withdrawn from consideration but not canceled: None.
3. Claims pending: 1-47.
4. Claims allowed: None.
5. Claims rejected: 1-47.

C. Claims On Appeal

The claims on appeal are claims 1-47.

IV. STATUS OF AMENDMENTS

Applicant did not file an Amendment After Final Rejection.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The evaluation of variability in heart period, arterial blood pressure, and electrocardiography (ECG) QT interval data is a powerful means of non-invasively monitoring autonomic nervous system activity as the body responds to varying actual or perceived stressors. However, conventional means of analysis have proven challenging to interpret under a variety of conditions relevant to telemedicine applications. Traditional

means of monitoring variability involve evaluation of the time interval data of successive events in the frequency domain. The frequency spectrum, however, is dominated by very low frequency events that can obscure critical frequency bands in the 0.04 to 0.5 Hz region. This is especially true for data acquired over short time intervals where the focus is on higher frequency information (specification, paragraph [0004]).

To overcome the above limitation, the variance in time interval between two events, e.g., the time interval difference between adjacent heart beats (or interval delta), rather than the time interval itself, has been found to greatly simplify interpretation of the variability data. Further, the use of interval delta measurements significantly improves the reliability of individual measurements in providing physiologically meaningful information for any heart rate measurement of sufficient time precision (specification, paragraph [0004]).

High time precision heart cycle timing is used for, inter alia, the evaluation of heart rate variability measurements previously achievable with sufficient precision through relatively cumbersome electrocardiography measurements. The present invention has further refined heart rate variability power spectrum analysis to suppress very low frequency (VLF) and ultra low frequency (ULF) components that reside below 0.04 Hz. The heart rate variability analysis described by the present invention and referred to as delta heart rate variability (ΔHRV or DHRV) allows a clear representation and simplified assessment of the more physiologically established low frequency (LF) and high frequency (HF) components (specification, paragraph [0005]).

For heart rate variability (HRV) analysis and delta heart rate variability (ΔHRV) analysis only the primary heart vibration array, S1, is required. First, an array of heart period (HP) intervals is created by taking the difference between successive elements of the S1 array. This is shown in box 210, Fig. 2. The HP array provides the data required to perform a heart rate variability (HRV) evaluation process 300, Fig. 3. To perform a delta heart rate variability (ΔHRV) evaluation process 400, Fig. 4, the HP array is further processed to obtain a delta heart period (ΔHP) array. This is shown in box 212, Fig. 2, where successive HP intervals determined from the S1 array are differenced to determine a ΔHP array. Other patterns of intervals can also be implemented. For instance, every other HP interval can be

differenced to create the ΔHP array. Or, every third HP interval can be differenced to create the Δ HP array. The ΔHP array is then passed to the process that evaluates delta heart rate variability (ΔHRV) (specification, paragraph [0024]).

Referring now to Fig. 3, the input data array is typically oversampled and linearly interpolated 302 to increase the number of data values for subsequent calculations. The system operator then defines a time interval, n, to be evaluated 304. The array is then set to 2n data points 306 by either padding the array or truncating the array as appropriate. The interpolated data set of 2n points is then subjected to a fast fourier transform (FFT) 308 to obtain a power spectrum for the heart data. This effectively converts the heart data from the time domain to the frequency domain for additional analysis. The power spectrum data is integrated 310 to obtain discrete power readings in terms of s^2/Hz. Low frequency (LF) readings are integrated between approximately 0.04 to 0.15 Hz. High frequency (HF) readings are integrated between approximately 0.15 to 0.4 Hz. Very High frequency (VHF) readings are integrated between approximately 0.4 to 1.0 Hz (specification, paragraph [0028]).

Fig. 4 is a data flow diagram of the delta heart rate variability (ΔHRV) evaluation process 400. This process uses as its input data the ΔHP array recorded by box 212 of Fig. 2. The process illustrated in Fig. 4 is identical to that of Fig. 3. The only difference is the original set of input heart data. Rather than using the heart period (HP) interval array, the ΔHRV evaluation process 400 uses the ΔHP array. The HRV analysis extracts information based on the interval between successive heartbeats while the ΔHRV analysis extracts information based on the power readings derived from the interval difference in adjacent heartbeats. Thus, while the mathematical manipulations of the input data set are the same, the input data set itself is different leading to additional inferences and conclusions regarding the original set of acquired heart data from box 120 of Fig. 1 (specification, paragraph [0031]).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. § 103 Rejection:

Whether claims 1-47 are unpatentable under 35 USC 103(a) over the combination of Meyer (US 6,308,098) in view of Sun et al. (US 6,811,536).

VII. ARGUMENT

A. § 103 Rejection:

Meyer's preferred physiological measurement is based on intracardial impedance measurements which are used to measure the cardiac cycle (heart period) from which heart rate variability is evaluated. Sun et al. prefer to use electrocardiography or sphygmography (arterial pressure recorded as a function of time) which, again, is used for heart rate variability measurements. The difference between the cited references and Applicant's invention relative to the fundamental physiological measurement is, therefore, that in the case of Applicant's invention microwave skin surface monitoring is used to measure the time interval between heart beats, valve events within a heart beat, and respiration events whereas Meyer and Sun et al. use established methods to measure the time interval between heart beats only.

Once the three physiological measures are isolated in the frequency domain, the heart rate information is subjected to established or easily derivable forms of established heart rate variability measures relating to, what is known in the art as, the low and high frequency powers (normalized or not). It is also known and common in the art to further subdivide the low frequency region (the very low frequency, the ultra low frequency, etc.) but there has been found to be little value in this exercise as the data is too easily subject to non-physiological interferences using the microwave sensor.

In contrast to the limited value of lower frequency data using the microwave sensor, Applicant has found that the region above 0.4 Hz contains important information that has not been recognized in the prior art. Applicant, therefore, defined the frequency range 0.4 – 1.0 Hz as the "very high frequency or VHF" region. This region corresponds to beat-to-beat variability which is higher in frequency and distinct from high frequency (HF) variability (0.15 – 0.4 Hz). The HF heart rate variability is known in the open literature to be coupled to the respiration rate (i.e., the frequency of the HF band corresponds with the respiration rate of the subject). The VHF and HF frequency regions, therefore, have different underlying neurophysiological origins. While Applicant has observed data presented in the art that

shows power (bands) at frequencies > 0.4 Hz, it is ignored. Data that Applicant has collected indicates that this VHF data is physiologically important.

The frequency ranges in Applicant's application are defined relative to human subjects only. Animal subjects possess different heart rates, respiration rates, and heart rate variability parameters. In rats, for example, heart rate and respiration rate are higher than in humans. Heart rate variability parameters also shift toward higher frequencies in rats. Consequently, the defined LF and HF regions are shifted in frequency to accommodate this physiological difference. This is well known in the art. Therefore, the Sun et al. reference for higher frequency measurements when monitoring Sprague-Dawley rats is not a reference to the monitoring of what Applicant has defined as the VHF region, but rather to the intrinsic physiology difference of the rat relative to humans. Sun et al. do not indicate a recognition that they have identified heart rate variability information at higher frequency than the respiration frequency (i.e., the HF frequency) and, therefore, Sun et al. does not disclose what is claimed related to VHF in Applicant's invention.

During the course of investigation, Applicant found that data processed using established heart rate variability measures with the microwave sensor were sensitive to interferences at frequencies lower than the LF band that complicated interpretation of the results generated. To simplify the results, the data was subject to differentiation, i.e., the time interval difference between adjacent heart beats (or interval delta) was used for heart rate variability analysis rather than the heart period itself. This processing step dramatically suppresses low frequency interferences (i.e., it acts as a high pass filter). Suppression of the low frequency interferences was the purpose of the differential analysis, for which it was successful. However, the differential analysis step had the benefit of enhancing the VHF signal strength which is the true origin of Applicant's realization and recognition of the importance of this frequency range.

The differential analysis step is not an established process or recognized as valuable in analysis of heart rate variability in the prior art. In fact, the differential analysis step's very nature suppresses low frequency signals that are believed to be of value to some using other methods of physiological monitoring. As a consequence, investigators have not yet realized the value in differential analysis. Additionally, Applicant believes that the differential analysis method will prove to be useful using sensor technologies other than the

microwave sensor including those that are stable in laboratory environments but that are subject to low frequency interferences when used in "noisy" environments. Therefore, Applicant submits that the differential analysis processing step, as recited in all independent claims, is novel and a significant contribution to the measurement and interpretation of heart rate variability. Applicant's invention goes further to apply these same concepts to respiration and heart valve event variability analyses.

Acquisition of heart period, heart valve event timing, and respiration frequency using a single skin surface vibration/motion sensor, isolating the physiological measurement (heart rate, heart valve event, and respiration), subjecting each to differential variability analysis, and recognizing and including the VHF region for heart rate variability and differential heart rate variability each represent novel aspects of Applicant's invention relative to Meyer and Sun et al. Therefore, the combination of Meyer and Sun et al. cannot render obvious claims 1-47.

VIII. CLAIMS

A copy of the claims involved in the present appeal is attached hereto as the Claims Appendix .

Dated: June 17, 2008

Respectfully submitted,

Johns Hopkins University
Applied Physics Laboratory

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APPENDIX A

Claims Involved in the Appeal of Application Serial No. 10/687,230

1. A non-invasive health monitor device comprising:

a processor;

a processor readable storage medium;

code recorded in the processor readable storage medium to create a first array of data based on discretely recorded time events in which each element of the first array is representative of a time when an event took place;

code recorded in the processor readable storage medium to create a second array of data in which each element of the second array is an interval representative of the difference between successive elements of the first array;

code recorded in the processor readable storage medium to create a third array of data in which each element of the third array is a delta interval representative of the difference between successive elements of the second array;

code recorded in the processor readable storage medium to perform a fast fourier transform (FFT) to obtain power spectrum data representative of the third array; and

code recorded in the processor readable storage medium to integrate the power spectrum data over frequency ranges of interest to obtain discrete power values for said frequency ranges of interest.

2. A non-invasive health monitor device to assist in cardiac evaluation comprising:

a processor;

a processor readable storage medium;

code recorded in the processor readable storage medium to create a first array of heart vibrations based on discretely recorded heartbeats in which each element of the first array is representative of a time when a heartbeat took place;

code recorded in the processor readable storage medium to create a heart period array in which each element is a heart period interval representative of the difference between successive heartbeats of the first array of heart vibrations;

code recorded in the processor readable storage medium to create a delta heart period interval array in which each element is a delta heart period interval representative of the difference between successive elements of the heart period interval array;

code recorded in the processor readable storage medium to perform a fast fourier transform (FFT) to obtain power spectrum data representative of the delta heart period interval array; and

code recorded in the processor readable storage medium to integrate the power spectrum data over one or more frequency ranges of interest to obtain discrete power values for said one or more frequency ranges of interest.

3. The non-invasive health monitor device of claim 2 wherein the frequency ranges of interest include a low frequency (LF) range, a high frequency (HF) range, and a very high frequency (VHF) range.

4. The non-invasive health monitor device of claim 3 further comprising:

code recorded in the processor readable storage medium to calculate a total power, TP, value that is the sum of the LF, HF, and VHF power values.

5. The non-invasive health monitor device of claim 3 further comprising:

code recorded in the processor readable storage medium to calculate a power ratio value that is equal to LF / HF.

6. The non-invasive health monitor device of claim 4 further comprising:

code recorded in the processor readable storage medium to calculate a normalized LF power value that is equal to LF / TP.

7. The non-invasive health monitor device of claim 4 further comprising:

code recorded in the processor readable storage medium to calculate a normalized HF power value that is equal to HF / TP.

8. The non-invasive health monitor device of claim 4 further comprising:

code recorded in the processor readable storage medium to calculate a normalized VHF power value that is equal to VHF / TP.

9. The non-invasive health monitor device of claim 3 wherein the LF range is approximately 0.04 to 0.15 Hz.

10. The non-invasive health monitor device of claim 3 wherein the HF range is approximately 0.15 to 0.4 Hz.

11. The non-invasive health monitor device of claim 3 wherein the VHF range is approximately 0.4 to 1.0 Hz.

12. A non-invasive health monitor device to assist in respiration evaluation comprising:

a processor;

a processor readable storage medium;

code recorded in the processor readable storage medium to create a first array of respiration events based on discretely recorded body motions in which each element of the first array is representative of a time when a respiration event took place;

code recorded in the processor readable storage medium to create a respiration period interval array in which each element is a respiration period interval representative of the difference between successive elements of the first array of respiration events;

code recorded in the processor readable storage medium to create a delta respiration period interval array in which each element is a delta respiration period interval representative of the difference between successive elements of the respiration period interval array;

code recorded in the processor readable storage medium to perform a fast fourier transform (FFT) to obtain power spectrum data representative of the delta respiration period interval array; and

code recorded in the processor readable storage medium to integrate the power spectrum data over a defined range of interest to obtain a discrete power value.

13. A non-invasive health monitor device to assist in cardiac evaluation comprising:

a processor;

a processor readable storage medium;

code recorded in the processor readable storage medium to create an array of first heart vibrations based on discretely recorded heartbeats in which each element of the first array is representative of a time when a first heart vibration of a heartbeat took place;

code recorded in the processor readable storage medium to create an array of second heart vibrations having an element to element association with the array of first heart vibration, said array of second heart vibrations representative of a time when a second heart vibration of a heartbeat took place;

code recorded in the processor readable storage medium to create a ventricular systole interval array in which each element is an interval representative of the time difference between the second and first heart vibrations of each heartbeat in the second and first heart vibration arrays;

code recorded in the processor readable storage medium to create a delta ventricular systole interval array in which each element is a delta ventricular systole interval representative of the difference between successive elements of the ventricular systole interval array;

code recorded in the processor readable storage medium to perform a fast fourier transform (FFT) to obtain power spectrum data representative of the delta ventricular systole interval array; and

code recorded in the processor readable storage medium to integrate the power spectrum data over one or more frequency ranges of interest to obtain discrete power values for said one or more frequency ranges of interest.

14. The non-invasive health monitor device of claim 13 wherein the power spectrum frequency ranges of interest include a low frequency (LF) range, a high frequency (HF) range, and a very high frequency (VHF) range.

15. The non-invasive health monitor device of claim 14 further comprising:

code recorded in the processor readable storage medium to calculate a total power, TP, value that is the sum of the LF, HF, and VHF power values.

16. The non-invasive health monitor device of claim 14 further comprising:

code recorded in the processor readable storage medium to calculate a power ratio value that is equal to LF / HF.

17. The non-invasive health monitor device of claim 15 further comprising:

code recorded in the processor readable storage medium to calculate a normalized LF power value that is equal to LF / TP.

18. The non-invasive health monitor device of claim 15 further comprising:

code recorded in the processor readable storage medium to calculate a normalized HF power value that is equal to HF / TP.

19. The non-invasive health monitor device of claim 15 further comprising:

code recorded in the processor readable storage medium to calculate a normalized VHF power value that is equal to VHF / TP.

20. The non-invasive health monitor device of claim 14 wherein the LF range is approximately 0 to 0.15 Hz.

21. The non-invasive health monitor device of claim 14 wherein the HF range is approximately 0.15 to 0.4 Hz.

22. The non-invasive health monitor device of claim 14 wherein the VHF range is approximately 0.4 to 1.0 Hz.

23. A non-invasive health monitor device comprising:

a processor;

a processor readable storage medium;

code recorded in the processor readable storage medium to create a first array of data based on discretely recorded time events in which each element of the first array is representative of a time when an event took place;

code recorded in the processor readable storage medium to create a second array of data in which each element of the second array is an interval representative of the difference between successive elements of the first array;

code recorded in the processor readable storage medium to create a third array of data in which each element of the third array is a delta interval representative of the difference between non-successive elements of the second array;

code recorded in the processor readable storage medium to perform a fast fourier transform (FFT) to obtain power spectrum data representative of the third array; and

code recorded in the processor readable storage medium to integrate the power spectrum data over frequency ranges of interest to obtain discrete power values for said frequency ranges of interest.

24. A method of monitoring health non-invasively comprising:

creating a first array of data based on discretely recorded time events in which each element of the first array is representative of a time when an event took place;

creating a second array of data in which each element of the second array is an interval representative of the difference between successive elements of the first array;

creating a third array of data in which each element of the third array is a delta interval representative of the difference between successive elements of the second array;

performing a fast fourier transform (FFT) on the third array to obtain power spectrum data representative of the third array; and

integrating the power spectrum data over frequency ranges of interest to obtain discrete power values for said frequency ranges of interest.

25. A method of monitoring health non-invasively to assist in cardiac evaluation comprising:

creating a first array of heart vibrations based on discretely recorded heartbeats in which each element of the first array is representative of a time when a heartbeat took place;

creating a heart period array in which each element is a heart period interval representative of the difference between successive elements of the first array of heart vibrations;

creating a delta heart period interval array in which each element is a delta heart period interval representative of the difference between successive elements of the heart period interval array;

performing a fast fourier transform (FFT) on the delta heart period interval array to obtain power spectrum data representative of the delta heart period interval array; and

integrating the power spectrum data over one or more frequency ranges of interest to obtain discrete power values for said one or more frequency ranges of interest.

26. The method of claim 25 wherein the frequency ranges of interest include a low frequency (LF) range, a high frequency (HF) range, and a very high frequency (VHF) range.

27. The method of claim 26 further comprising:

calculating a total power, TP, value that is the sum of the LF, HF, and VHF power values.

28. The method of claim 26 further comprising:

calculating a power ratio value that is equal to LF / HF.

29. The method of claim 27 further comprising:

calculating a normalized LF power value that is equal to LF / TP.

30. The method of claim 27 further comprising:

calculating a normalized HF power value that is equal to HF / TP.

31. The method of claim 27 further comprising:

calculating a normalized VHF power value that is equal to VHF / TP.

32. The method claim 26 wherein the LF range is approximately 0.04 to 0.15 Hz.

33. The method of claim 26 wherein the HF range is approximately 0.15 to 0.4 Hz.

34. The method of claim 26 wherein the VHF range is approximately 0.4 to 1.0 Hz.

35. A method of monitoring health non-invasively to assist in respiration evaluation comprising:

creating a first array of respiration events based on discretely recorded body motions in which each element of the first array is representative of a time when a respiration event took place;

creating a respiration period interval array in which each element is a respiration period interval representative of the difference between successive elements of the first array of respiration events;

creating a delta respiration period interval array in which each element is a delta respiration period interval representative of the difference between successive elements of the respiration period interval array;

performing a fast fourier transform (FFT) on the delta respiration period interval array to obtain power spectrum data representative of the delta respiration period interval array; and

integrating the power spectrum data over a low frequency (LF) range of interest to obtain a discrete power value.

36. The method of claim 35 wherein the LF range is approximately 0.04 to 0.3 Hz.

37. A method of monitoring health non-invasively to assist in cardiac evaluation comprising:

creating a first array of heart vibrations based on discretely recorded heartbeats in which each element of the first array is representative of a time when a ventricular heart vibration of a heartbeat took place;

creating a second array of heart vibrations having an element to element association with the first array of heart vibrations, said second array of heart vibrations representative of a time when a systolic heart vibration of a heartbeat took place;

creating a ventricular systole interval array in which each element is an interval representative of the time difference between the second and first heart vibrations of each heartbeat in the second and first arrays;

creating a delta ventricular systole interval array in which each element is a delta ventricular systole interval representative of the difference between successive elements of the ventricular systole interval array;

performing a fast fourier transform (FFT) on the delta ventricular systole interval array to obtain power spectrum data representative of the delta ventricular systole interval array; and

integrating the power spectrum data over one or more frequency ranges of interest to obtain discrete power values for said one or more frequency ranges of interest.

38. The method of claim 37 wherein the frequency ranges of interest include a low frequency (LF) range, a high frequency (HF) range, and a very high frequency (VHF) range.

39. The method of claim 38 further comprising:

calculating a total power, TP, value that is the sum of the LF, HF, and VHF power values.

40. The method of claim 38 further comprising:

calculating a power ratio value that is equal to LF / HF.

41. The method of claim 39 further comprising:

calculating a normalized LF power value that is equal to LF / TP.

42. The method of claim 39 further comprising:

calculating a normalized HF power value that is equal to HF / TP.

43. The method of claim 39 further comprising:

calculating a normalized VHF power value that is equal to VHF / TP.

44. The method of claim 38 wherein the LF range is approximately 0.04 to 0.15 Hz.

45. The method of claim 38 wherein the HF range is approximately 0.15 to 0.4 Hz.

46. The method of claim 38 wherein the VHF range is approximately 0.4 to 1.0 Hz.

47. A method of monitoring health non-invasively comprising:

creating a first array of data based on discretely recorded time events in which each element of the first array is representative of a time when an event took place;

creating a second array of data in which each element of the second array is an interval representative of the difference between successive elements of the first array;

creating a third array of data in which each element of the third array is a delta interval representative of the difference between non-successive elements of the second array;

performing a fast fourier transform (FFT) on the third array of data to obtain power spectrum data representative of the third array of data; and

integrating the power spectrum data over frequency ranges of interest to obtain discrete power values for said frequency ranges of interest.

EVIDENCE APPENDIX

No evidence pursuant to §§ 1.130, 1.131, or 1.132 or entered by or relied upon by the examiner is being submitted.

RELATED PROCEEDINGS APPENDIX

No related proceedings are referenced in II. above, hence copies of decisions in related proceedings are not provided.